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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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AKIN GUMP STRAUSS HAUER & FELD L.L.P.  
ONE COMMERCE SQUARE  
2005 MARKET STREET, SUITE 2200  
PHILADELPHIA, PA 19103-7013

EXAMINER

OLSEN, KAJ K

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 09/11/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/800,014

Applicant(s)

GEPHART ET AL.

Examiner

Kaj Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 39-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-39, drawn to medical diagnostic system, classified in class 204, subclass 406.
  - II. Claims 39-60, drawn to diagnostic test cell, classified in class 204, subclass 403.01.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination doesn't require a calibration or specimen capsule. The subcombination has separate utility such as with a lab bench mounted analyzer.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Leslie Kasten Jr. on 9-2-2003 a provisional election was made without traverse to prosecute the invention of group I, claims 1-38.

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Affirmation of this election must be made by applicant in replying to this Office action. Claims 39-60 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-12, 17-19, 24, 26-28, 30 and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Lauks et al (USP 5,096,669).

8. Lauks discloses a system for conducting medical diagnostic tests. The system comprises a hand held portable instrument 150 that engages a disposable test cell 10 for performing a diagnostic tests (see abstract). Lauks also discloses that the test cell receives fluid to be diagnostically tested and is sized and shaped for engagement with the instrument (col. 10, lines 50-56). With respect to the use of identification information indicative of the particular diagnostic test to be performed, the use of notches to control which test is to be performed (col.

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6, lines 54-68) would read on the claimed identification information giving the claim language its broadest reasonable interpretation.

9. With respect to claim 2, see fig. 1.

10. With respect to claim 3, the notches (36,38) would appear to prevent insertion of the test cell in any other orientation.

11. With respect to claim 4, see col. 11, lines 33-47.

12. With respect to claim 5, see col. 6, lines 54-68.

13. With respect to claim 6, see col. 4, lines 26-31.

14. With respect to claims 7-12 (those limitations that don't merely cite intended use of the instrument or calibration fluid), see col. 4, line 35 through col. 5, line 14.

15. With respect to claim 17, see col. 11, lines 11-13.

16. With respect to claim 18, see col. 12, line 1-3.

17. With respect to claim 19, the various notches for defining the type of analysis to be done reads on "indicia" giving the claim language its broadest reasonable interpretation (however, see rejections for claims 20-22 below).

18. With respect to claim 24, see fig. 1.

19. With respect to claims 26-28 and 30, see col. 10, lines 30-44.

20. With respect to claims 36 and 37, comparing conductivity or measuring current is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

21. With respect to claim 38, see abstract.

***Claim Rejections - 35 USC § 103***

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

24. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks in view of Tomita (USP 4,797,188).

25. Lauks teaches all the limitations of the claims, but does not explicitly provide the detailed structure for the test cell. Tomita teaches in an alternate cell for monitoring the constituents in aqueous samples that a typical test cell for measuring concentrations of things such as potassium includes an electrolyte (i.e. an internal solution) 19 coated over one of the electrodes (fig. 1). Internal solutions are a well established means for ensuring appropriate electrochemical contact between the metal electrode and the sample and it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Tomita for the apparatus of Lauks in order to ensure appropriate electrochemical contact between the metal

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electrode and the sample. Tomita also teaches the use of a gelled form of the internal solution as well as an ion selective membrane 20 which has been impregnated with an appropriate chemical species over that gelled solution (col. 4, line 62 through col. 5, line 38).

26. Claims 20-23 and 35 (and claim 19 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks in view of Ozawa et al (USP 5,690,893).

27. Lauks set forth all the limitations of the claims, but did not explicitly set forth the use of a reader or a barcode. Ozawa teaches in an alternate electrochemical system that other indicia for identifying details about the particular test cell being manipulated. Those other indicia include bar codes and programmable memory (col. 1, lines 18-23 and col. 5, line 59 through col. 6, line 14). These other means of indicating to the instrument details about the particular test cell allow one to provide more information than is possible with the notches of Lauks including correction and calibration factors, and sensor lot numbers. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Ozawa for the system of Lauks in order to further improve the measurement accuracy of the individual sensors. With respect to having every identification information being unique, if the information contained calibration or correction information unique to that particular test cell, then every identification information would be unique.

28. With respect to claim 35, see Ozawa, col. 4, lines 18-40.

29. Claims 25 and 29 (and claims 27 and 28 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks in view of Jakubowicz et al (USP 4,798,705).

30. Lauks set forth all the limitations of the claims, but did not explicitly set forth the use of either a liquid crystal display or a thermal printer. Jakubowicz discloses that both those forms

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displays and printers are well known in the analytical art (col. 3, lines 3-6). With respect to claims 27 and 28 in the alternative), Jakubowicz also shows that the printer and keyboard of a system can be integrated into the instrument (fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Jakubowicz for the system of Lauks because the substitution of one known means for display or printer for another known means requires only routine skill in the art. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Jakubowicz for the system of Lauks because integrating the keyboard and printer into the single device simplifies the system making it easier to handle.

31. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks in view of Betts et al (USP 5,405,510).

32. Lauks set forth all the limitations of the claims, but did not explicitly identify the use of the RS 232 interface or the use of an internal power source. Betts discloses that both that particular interface as well as the use of batteries is well known in the art (col. 14, lines 6-9 and col. 19, lines 15-18). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Betts for the system of Lauks because the use of standard interfaces and power sources requires only routine skill in the art. With respect to the batteries being rechargeable, rechargeable batteries are an obvious and conventional form of battery and it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize them because they would save the system operator money over the long term.



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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Nam Nguyen, can be reached at (703) 308-3322.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for regular communications is (703) 305-3599 and the fax number for after-final communications is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.

A handwritten signature in black ink, appearing to read 'Kaj Olsen', with a stylized flourish extending from the end.

Kaj K. Olsen  
Patent Examiner  
AU 1753  
September 4, 2003